

K 081501 (pg. 1 of 2)

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.

Preparation Date: June 27, 2008
Applicant/Sponsor: Biomet Spine
100 Interpace Parkway
Parsippany, NJ 07054
Contact Person: Vivian Kelly
Phone: 973-299-9300 x2214
Fax: 973-257-0232
Trade name: Solitaire™ Anterior Spinal System
Common Name: Intervertebral Body Fusion Device, Vertebral Body Replacement Device
Classification Name: Intervertebral Body Fusion Device, 21 CFR 888.3080; Spinal Intervertebral Body Fixation Orthosis, 21 CFR 888.3060
Device Panel /Product Code: Orthopedic MAX, MQP

Device Description:

The components of the Solitaire™ Anterior Spinal System are comprised of Titanium alloy and are inserted into the intervertebral body space of the lumbosacral spine with bone graft material. The system consists of a spacer with radiographic markers and three bone screws.

Indications for Use:

The Solitaire Anterior Spinal System is indicated for vertebral body replacement and intervertebral fusion. When used for vertebral body replacement, the Solitaire Anterior Spinal System is indicated for use in the thoracolumbar spine (i.e., T10 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Solitaire System is also indicated for treating fractures of the thoracic and lumbar spine. The Solitaire System is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.

As an intervertebral body fusion device designed for use with autograft, the Solitaire Anterior Spinal System is indicated for stand-alone intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

Summary of Technologies:

The technological characteristics (material, design and sizing) of the Solitaire™ Anterior Spinal System are the same as, or similar to, the predicate devices.

Substantial Equivalence:

The Solitaire™ Anterior Spinal System is substantially equivalent to its predicate devices with respect to intended use and indications, technological characteristics, and principles of operation and do not present any new issues of safety or effectiveness. An example of another predicate intervertebral body fusion device distributed for the similar indications include the InterPlate™ Interbody Fusion Device by RSB Spine, LLC (K071922) while the Solitaire™ Anterior Spinal System from Interpore Cross Intl and EBI LP (K022143 & K062810) have similar design features. Based upon the mechanical testing, the Solitaire™ Anterior Spinal System is substantially equivalent for its intended use to other spacers currently on the market.



JUL 31 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biomet Spine
% Ms. Vivian Kelly, MS, RAC
Regulatory Affairs Project Manager
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K081501
Trade Name: Solitaire Anterior Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Names: Spinal intervertebral fusion orthosis
Regulatory Class: Class II
Product Code: MAX, MQP
Dated: May 12 2008
Received: May 19, 2008

Dear Ms. Kelly:

This letter corrects our substantially equivalent letter of July 2, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA) application. You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or 240-276-3150 or at its Internet address: <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K081501

Device Name: Solitaire™ Anterior Spinal System

Indications for Use:

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Prescription Use ☒
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
 (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH/Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number 12081501